

REMARKS

Reconsideration is respectfully requested. Claims 20, 22, 23 and 30-36 are pending. Claims 1-19, 21 and 24-29 have been canceled. Claim 30 has been amended for clarification. No new matter has been introduced.

Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Information Disclosure Statement

The Examiner objected to the references cited in the specification because all references cited in an application must be submitted in the form of a separate paper, and not incorporated into the specification, in accordance with 37 C.F.R. § 1.98(b) and M.P.E.P. § 609(A)(1).

Applicants submit a Supplemental Information Disclosure Statement with a listing of those prior art material to patentability incorporated into the specification, but not previously submitted in a PTO-1449 or PTO-892. Therefore, Applicants respectfully request consideration of the listed references, and withdrawal of the objection to the Information Disclosure Statement.

Claims Rejection Under 35 U.S.C. § 112

Claims 20, 22, 23 and 30-36 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement on the basis that claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed the invention. Specifically, the Examiner objects to the change to the claim language to read on “passivation monolayer” replacing self assembled monolayer (SAM), on the basis that the specification implies that the passivation agent is a spacer not a replacement for the SAM. The Examiner also alleges that it is deemed a new matter. The rejection is traversed as applied to Claims 20, 22, 23 and 30-36.

First of all, Applicants submit that the determination of whether a claim amendment meet the written description requirement is based on the amendment being made, not how it is made. The written description requirement involves the question of whether the subject matter of a claim is supported by the disclosure of an application as filed. M.P.E.P. § 2163.01. Whether a term replaced by amendment has the same definition as the replacing term is irrelevant. The focus of review should be the amended claims, not how they are amended.

In the previous response to the Office Action mailed April 9, 2003 (mailed on August 6, 2003, filed on August 11, 2003) and response to Notice of Non-Compliance mailed April 22, 2004 (mailed on May 24, 2004, filed on May 26, 2004), Applicants have amended claims to use the term “passivation agent” and removed the term “self assembled monolayer (SAM).” After such amendment, the proper inquiry should be whether “passivation agent,” as a limitation, is supported by the disclosure. It is not proper to inquire whether “self assembled monolayer (SAM)” is supported by the disclosure, or whether the terms are interchangeable as supported by the disclosure, because the term “self assembled monolayer (SAM)” is no longer a limitation of the pending claims, and whether the two terms are interchangeable is no longer an issue.

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter. M.P.E.P. § 2163.06. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Claims 20 and 30 require:

a passivation agent monolayer comprising at least a covalently attached first passivation species and a covalently attached second passivation species comprising a protein binding ligand.

There is ample description of “passivation agent monolayer” in the specification. For example, the specification states:

[i]n a preferred embodiment, the electrode further comprises a passivation agent, preferably in the form of a monolayer on the electrode surface A passivation agent layer facilitates the maintenance of the target analyte away from the electrodethe monolayer of passivation agent is preferably tightly packed in a uniform layer on the electrode surface, such that a minimum of “holes” exist.

See page 34, lines 10-19.

The specification thus provides express written support for passivation agent, one embodiment of which is a monolayer. A passivation agent monolayer is thus sufficiently described.

The specification also discloses that “the passivation agent themselves may in fact be either (1) conducting or (2) nonconducting, i.e. insulating, molecules.” *See page 34, lines 23-25.* *See also page 35, lines 28-29 (“The monolayer may comprise a single type of passivation agent, including insulator, or different types,”) and page 35, lines 35-36 (“The passivation agents are generally attached to the electrode in the same manner as the conductive oligomer, and may use the same ‘A’ linker as defined above.”)*

Applicants have thus satisfied the written description requirement. Therefore, Applicants request the withdrawal of this ground for rejection.

Claim Rejection Under 35 U.S.C. § 103(a)

When rejecting claims under 35 U.S.C. §103, the Examiner bears the burden of establishing a *prima facie* case of obviousness. See, e.g., *In re Bell* 26 USPQ2d 1529 (Fed. Cir. 1993); M.P.E.P. § 2142. To establish a *prima facie* case, three basic criteria must be met: (1) the prior art reference(s) must teach or suggest each and every limitation of the rejected claims; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine their teachings; and (3) there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not in Applicants’ disclosure. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991); M.P.E.P. § 2142.

A. Claims 20, 30, 34 and 36

Claims 20, 30, 34 and 36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollis et al. (WO 93/22678) (“*Hollis*”) in view of *Agladze* (Metallurgy and Foundry Engineering (1997) 23(2), 127-137) (“*Agladze*”)—Abstract only. The rejection is traversed as applied to Claims 20, 30, 34 and 36.

1. The Examiner incorrectly cites only the Abstract of *Agladze*.

The Examiner has only cited the Abstract of *Agladze* as reference.

Citation of and reliance upon an abstract without citation of and reliance upon the underlying scientific document is generally inappropriate where both the abstract and the underlying document are prior art. See *Ex parte Jones*, 62 USPQ2d 1206, 1208 (Bd. Pat. App. & Inter. 2001) (unpublished). M.P.E.P § 706.02 II.

Applicants submit it is inappropriate for the Examiner to only cite the Abstract of *Agladze* as reference.

Enclosed is a copy of the full *Agladze* article as Exhibit A.

2. Neither *Hollis* nor *Agladze* teaches “a covalently attached first passivation species and a covalently attached second passivation species.”

Claims 34 and 36 depend on claims 20 and 30. Claim 20 and 30 require:

a passivation agent monolayer comprising at least a covalently attached first passivation species and a covalently attached second passivation species comprising a protein binding ligand; wherein said protein binding ligand is covalently attached to said electrode via a space.”

The Examiner alleges that *Hollis* teaches “an apparatus include a test chamber with . . . a passivation agent monolayer,” and “a binding ligand covalently attached to the electrode.” However, *Hollis* does not disclose “a covalently attached first passivation species and a covalently attached second passivation species.”

Hollis teaches “[p]assivating materials can be hydrophobic materials such as fluorine-terminated fluorocarbons or the derivatives or hexamethyldisilizane,” see page 29, line 13-16, and “passivating layer,” see page 29 line 29-30. However, *Hollis* does not expressly or implicitly

teach “a covalently attached first passivation species and a covalently attached second passivation species ” as claims 20 and 30 require. Although the term “passivation layer” is used by *Hollis*, there is simply no teaching of a covalently attached passivation species.

Similarly, *Agladze* fails to teach “a covalently attached first passivation species and a covalently attached second passivation species,” either expressly or inherently, as claims 20 and 30 require. Like *Hollis*, there is no teaching of a covalently attached “passivation species.”

The Examiner concedes that *Hollis* “differ from the instant invention in not specifically teaching that the passivation layer (passivation agent monolayer) comprises two passivation species,” and cites the abstract of *Agladze* for the proposition that *Agladze* “discloses that passivation films (layers) can modified [sic] electrode reactivity reaction via OH ions (species one) and anions (species two).”

The full text of *Agladze* teaches “it is reasonable to assume that primary passive film consist mainly of adsorbed hydroxide groups and ions adsorbed either according to solvent displacement or hydrogen-boning mechanism.” *See* page 132. It also teaches that such a film is a possible layer of adsorbed solvent molecules and ions form at the interface between the liquid face and solid phase of an electrode. *See* page 132. However, “adsorbed” is not “covalent”, and there is no teaching in *Agladze* about “a covalently attached first passivation species and a covalently attached second passivation species.”

3. Neither *Hollis* nor *Agladze* teaches “second passivation species comprising a protein binding ligand.”

As discussed above, *Hollis* teaches “[p]assivating materials can be hydrophobic materials such as fluorine-terminated fluorocarbons or the derivatives or hexamethyldisilizane” and “passivating layer.” However, *Hollis* also does not expressly or inherently teach a “second passivation species comprising a protein binding ligand” as claims 20 and 30 require.

Similarly, *Agladze* fails to teach “second passivation species comprising a protein binding ligand,” either expressly or inherently, as claims 20 and 30 require. Also as discussed above, the two alleged species are only anions and ions, which are not protein binding ligands.

Because *Hollis* does not expressly or implicitly teach “a covalently attached first passivation species and a covalently attached second passivation” and “a second species comprising a protein binding ligand,” and such failure is not cured by *Agladze*, *Hollis* and *Agladze* in combination fail to teach each and every limitation that claims 20 and 30, and claims 34 and 36 depend thereon, require.

4. There is no motivation or suggestion provided by the references to make first and second covalently attached passivation species or a second passivation species comprising a protein binding ligand.

As discussed above, the references do not disclose covalently attached passivation species of a second passivation species comprising a protein binding ligand, as claims 20 and 30 require. Thus there is no motivation or suggestion provided in the cited references to make the claimed invention.

Furthermore, *Agladze* is non-analogous art. In order to rely on a reference as a basis for rejection, the reference must either be in the field of Applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992); *See also Wang Laboratories Inc. v. Toshiba Corp.*, 993 F.2d 858 (Fed. Cir. 1993); and *State Contracting & Eng’g Corp. v. Condotte America, Inc.*, 346 F.3d 1057, 1069, (Fed. Cir. 2003). *Agladze* is in the field of metallurgy and foundry engineering, not in the field of biosensors based on electrochemical detection as the claimed invention. There is also no teaching in *Agladze* about “an apparatus for the detection of protein target analyte in a test sample.” The *Agladze* reference is, as the title shows, directed to “the corrosion and passivation process of iron group metals.” *See* page 127. Further, the “passivation species” of *Agladze* are not covalently attached. It is not pertinent to the particular problem the instant inventor was concerned - detection of a protein target analyte in a test sample. As such, *Agladze* is no-analogous art, and it does not provide the motivation or suggestion to combine with *Hollis*.

5. There is no reasonable expectation of success of making the unclaimed subject matter.

Likewise, the references do not provide the requisite reasonable expectation of success to include the undisclosed limitations. One of skill in the art would not have a reasonable expectation of success in altering the disclosed teachings to make the claimed invention.

Because the Examiner fails to establish a *prima facie* case, claims 20, 30, 34 and 36 are not obvious over *Hollis* in view *Agladze*, and the rejection on this ground should be withdrawn.

B. Claims 22, 23 and 31-33

Claims 22, 23 and 31-33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Hollis* in view of *Agladze*, and further in view of *Kayyem et al.* US Patent No. 6,221,583 (“*Kayyem*”) and *Kossovsky et al.* US Patent No. 5,585,646 (“*Kossovsky*”). The rejection is traversed as applied to Claims 22-23 and 31-33.

1. Under 35 U.S.C. § 103(c)(1), *Kayyem* cannot preclude patentability of the presently claimed invention under U.S.C. § 103.

35 U.S.C. § 103(c)(1) states:

[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Kayyem cannot be used in an obvious rejection under 35 U.S.C. § 103(a) if the reference could only qualify as prior art under 35 U.S.C. § 102(e), (f), or (g), and was owned by the same entity or subject to an obligation of assignment to the same entity as the instant application at the time the claimed invention was made.

Kayyem is not prior art under 35 U.S.C. § 102(a) because it was published on April 24, 2001, well after the filing date and priority date of the instant application. Likewise, *Kayyem* is not a prior art reference under 35 U.S.C. § 102(b) because *Kayyem* was not published or issued more than one year before the priority date of the instant application. *Kayyem* is also not a prior art reference under 35 U.S.C. § 102(c) or (d). Therefore, *Kayyem* could only be considered as alleged prior art under 35 U.S.C. §§ 102(e), (f), or (g).

In accordance with the requirements to establish common ownership articulated in M.P.E.P. § 706.02(l)(2), the instant U.S. Patent Application No. 09/096,593 and the *Kayyem* patent were, at the time the invention of the instant application was made, owned by Clinical Micro Sensors, Inc.

Therefore, according to U.S.C. § 103(c)(1), *Kayyem* cannot preclude patentability of the presently claimed invention under U.S.C. § 103. Because *Kayyem* is not proper reference, Applicant assume the rejection is over *Hollis* in view of *Agladze*, and further in view *Kossovsky*.

2. The references in combination do not teach each and every limitation of claims 22, 23 and 31-33.

Claim 22 and 23 depend on claim 20; claims 31-33 depend on claims 20 and 30. Because *Kayyem* is not properly considered prior art under 35 U.S.C. § 103(a) rejection, this rejection is actually over *Hollis* in view of *Agladze* and *Kossovsky*.

First, none of *Hollis*, *Agladze*, or *Kossovsky* teach the limitations the Examiner asserts are taught by *Kayyem*.

As discussed above, *Hollis* and *Agladze* do not expressly or implicitly teach “a covalently attached first passivation species and a covalently attached second passivation” and a “second species comprising a protein binding ligand.” Such failure is not cured by *Kossovsky*. *Kossovsky* teaches “bio-electronic devices in which electronically active biochemical materials are used in combination with a semiconductor material.” See col. 7, lines 7-9. However, *Kossovsky* does not teach any sensors, nor does it teach protein binding ligand. .

3. There is no motivation or suggestion provided by the references to make first and second covalently attached passivation species or a second passivation species comprising a protein binding ligand.

As discussed above, the references do not disclose covalently attached passivation species of a second passivation species comprising a protein binding ligand, as claims 20 and 30 require. Moreover, *Agladze* is no-analogous art, and it does not provide the motivation or suggestion to combine with *Hollis*. Thus there is no motivation or suggestion provided in the cited references to make the claimed invention.

4. There is no reasonable expectation of success of making the unclaimed subject matter.

Likewise, the references do not provide the requisite reasonable expectation of success to include the undisclosed limitations. One of skill in the art would not have a reasonable expectation of success in altering the disclosed teachings to make the claimed invention.

Because the Examiner fails to establish a *prima facie* case, claims 22, 23 and 31-33 are not obvious over *Hollis* in view *Agladze* and further in view *Kossovsky*, and the rejection on this ground should be withdrawn.

C. Claim 35

Claim 35 stands rejected under 35 U.S.C. § 103 (a) as allegedly unpatentable over *Hollis*, in view of *Agladze* and further in view of *Wohlstadter et al.* US Patent No. 6,090,545 (“*Wohlstadter*”). The rejection is traversed as applied to claim 35.

1. The references in combination do not teach each and every limitation of claims 35.

Claim 35 depends from claims 20 and 30.

As discussed above, *Hollis* and *Agladze* do not teach “a covalently attached first passivation species and a covalently attached second passivation species” and a “second species comprising a protein binding ligand.” Such failure is not cured by *Wohlstadter*. *Wohlstadter* teaches cassettes for conducting a plurality of electrochemiluminescence assays. *See* col. 7, lines 44-45. However, *Wohlstadter* does not teach passivation species or protein binding ligand.

2. There is no motivation or suggestion provided by the references to make first and second covalently attached passivation species or a second passivation species comprising a protein binding ligand.

As discussed above, the references do not disclose covalently attached passivation species of a second passivation species comprising a protein binding ligand, as claims 20 and 30 require. Moreover, *Agladze* is no-analogous art, and it does not provide the motivation or suggestion to combine with *Hollis*. Thus there is no motivation or suggestion provided in the cited references to make the claimed invention.

4. There is no reasonable expectation of success of making the unclaimed subject matter.

Likewise, the references do not provide the requisite reasonable expectation of success to include the undisclosed limitations. One of skill in the art would not have a reasonable expectation of success in altering the disclosed teachings to make the claimed invention.

Because the Examiner fails to establish a *prima facie* case, claims 22, 23 and 31-33 are not obvious over *Hollis* in view *Agladze* and further in view *Wohlstadter*, and the rejection on this ground should be withdrawn.

CONCLUSION

Applicants respectfully submit that the claims are in condition for allowance and early notification to that effect is respectfully requested. Please direct any calls in connection with this application to the undersigned attorney at (415) 781-1989.

Respectfully submitted,
DORSEY & WHITNEY LLP

Dated: December 22, 2005
Customer Number: 32940
Dorsey & Whitney LLP
Intellectual Property Department
555 California Street, Suite 1000
San Francisco, CA 94104-1513
Telephone: (415) 781-1989
Facsimile: (415) 398-3249

By:



Timothy A. Worrall, Reg. No. 54,552 for
Robin M. Silva, Reg. No. 38,304

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